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If you dialed in to this webinar on your phone please use the "raise your hand" button and we will open up your lines for you to ask your question to the group. (Left)

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### **Disclosures**

Camilla S. Graham, M.D., M.P.H. is a part time employee of TREK Therapeutics, a for-profit company, organized as a public benefit corporation.

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#### Ms. Jones

- 58 y/o woman with bipolar disease, GERD, arthritis
- IDU stopped 20 years ago; never heavy alcohol and none now
- Lives in a structured environment that supervises medications
- Diagnosed with hepatitis C in 2006
- Has seen Hepatology once, told she was not an interferon-alfa candidate, never went back
- Has liver enzymes checked by primary care once a year but no other specific intervention

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#### **Recent Exam and Labs**

- Seen for routine physical
- Reports mental health provider has recently increased one of her medications
- Complains of fatigue
- · No findings concerning for liver disease
- ALT 43, AST 60 (normal less than 40)
- WBC 4,300, Hgb 12.1, Platelets 145,000

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#### What are our concerns?

- She has cirrhosis
- · She needs treatment urgently
- · Ensure stability of mental health
- Have plan for close monitoring and intervention if she decompensates from a mental health perspective
- Drug-drug interactions with HCV treatment

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### **Barriers to HCV Care**

- 50% to 75% of people with HCV infection have not been diagnosed
  - 49% of persons with positive HCV antibodies have not had HCV RNA testing (viral load)<sub>1</sub>
    - 20% 30% spontaneously clear infection but must have viral load testing to know they do not have active infection
- Many patients never see a hepatitis C specialist
  - HCV specialists may include hepatology, some gastroenterology, some infectious disease, some internal medicine
  - 43% in a CDC-sponsored study; likely higher in certain groups 2
- If someone is deemed "not a treatment candidate" their candidacy is often not reviewed again
- Non-HCV specialists may not recognize signs of advanced liver disease nor advances in hepatitis C treatment

¹https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a4.htm; ²Foster; Dig Dis Sci 2016; 61:3469-3477

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## Barriers to HCV Care, cont'd.

- Patients may harbor beliefs about hepatitis C that make them reluctant to seek care:
  - · The treatment is worse than the HCV
    - · Interferon almost killed someone I know
  - Everyone has to get a liver biopsy
    - · Someone I knew almost died from a biopsy
- Doctors don't like to treat people like me
  - · I feel judged by hepatitis doctors
- Treatment is too expensive

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### What Doctors Like and Don't Like



#### l ike:

- Organized
- Neatly dressed
- Attentive
- Pleasant

#### Don't like:

- Disorganized
- Distracted
- Disrespectful looking
- Young people?

#### **Neutral:**

- Race
- Gender
- Class
- "Tough looking"

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## Patient Advocacy in Hepatitis C

- Provides services to patients as they navigate the healthcare system
- Works directly with patients to ensure that they have a voice in their care
- Works to make sure that patients have sufficient information to promote informed decision making
- Plays an informational role
- Is committed to helping patients make informed choices and access resources
- Ensures that a patient's wishes are the guiding force behind decisions affecting medical care and the withholding of care
- Collaborates effectively with other members of the healthcare team

https://pacboard.org/2016/03/09/patient-advocacy-vs-medical-advocacy-view-from-the-pacb/

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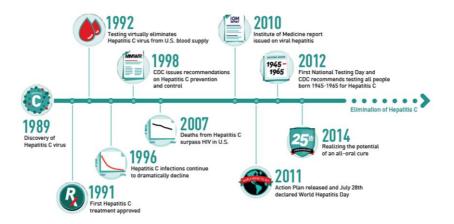
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## Patient Journey in Hepatitis C: Role of Patient Advocacy

-Coordinate -Address mental -Coordinate insurance health and/or appointments -Prior -Identify -Access to -Transportation authorization -Reduce risk screening primary care services -Childcare -Appeals at sites of of reinfection -Access to -Access to -Copay/financial -Address barriers/ care or HCV RNA -Avoidance nonassistance restrictions with co--Coordination of alcohol testing to judgmental -Housing -Medication with specialty located diagnose active and other HCV -Harm reduction delivery pharmacy services infection liver toxins provider services Regular follow up Screening -May -Describe support -Discuss and -Facilitate -Ongoing -Access to -General identify understandable services to HCV anticipate discussion of reinforcement health HCV information provider challenges side effects of liver health education providers in -Facilitate -Help develop -Adherence and harm about HCV -Anticipate communication primary solutions for tools reduction -Emotional fears of care, needle (as appropriate) adherence, -Communicate behaviors HCV support exchange, between providers ongoing care, other barriers to -Cirrhosis and OST competing -Ensure delivery adherence or liver cancer screening programs, of understandable medical and follow up Corrections patient information life issues follow up if bridge about labs, tests, -Help identify needed programs diagnoses, effects drug of HCV, role of interactions treatment

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## Working Towards the Elimination of Hepatitis C Virus (HCV)

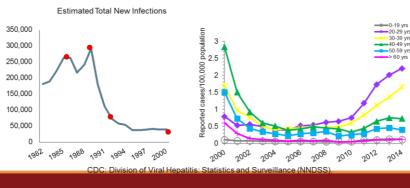


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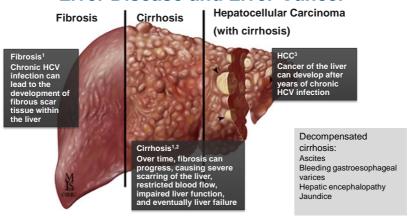
## Incidence of HCV Infection Decreased For Over 20 Years but is Now Increasing...

- · Decreased Rate of New Infections
  - 1986: Indirect blood screening for HCV/HIV prevention measures
  - 1989: Discovery of HCV
  - 1992: Anti-HCV serologic test licensed
  - 2001: Needlestick Safety and Prevention Act



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## **Chronic HCV Infection May Lead to Chronic Liver Disease and Liver Cancer**



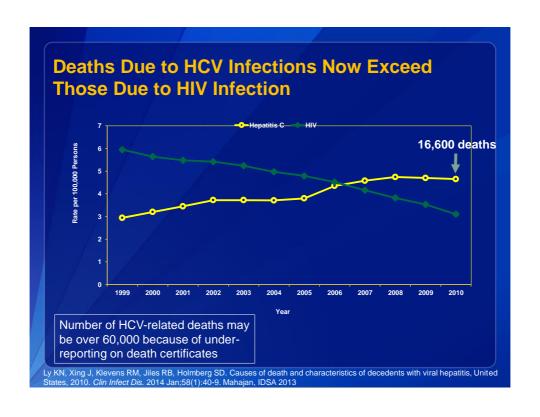
Chronic liver disease includes fibrosis, cirrhosis, and hepatic decompensation; HCC=hepatocellular carcinoma.

1. Highleyman L. Hepatitis C Support Project. http://www.hcvadvocate.org/hepatitis/factsheets\_pdf/Fibrosis.pdf. Accessed August 18, 2011

2. Bataller R et al. J Clin Invest. 2005;115:209-218;

3. Medline Plus. http://www.hm.nih.gov/mediineplus/enxy, article/000280.htm. Accessed August 28, 2012; 4. Centers for Disease Control and Prevention. http://www.odc.gov/hepatitis/HCV/HCVfaq.htm. Accessed May 8, 2012.

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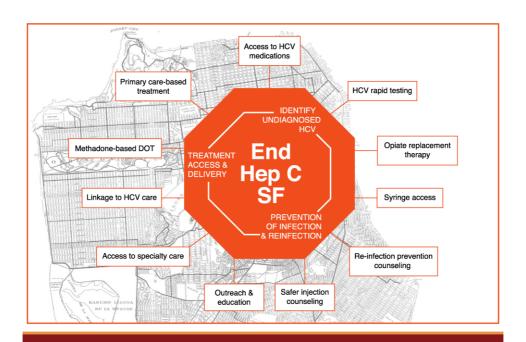
## National Academy of Sciences Consensus Report on Feasibility of HCV Elimination

- It is feasible to eliminate HCV in the US<sup>1</sup>
  - Approximately 10% of patients with HCV infection (including those currently undiagnosed) have been treated with DAAs in the US
- Barriers to elimination include:
  - Inadequate surveillance
  - Lack of screening
  - Insufficient linkage and retaining patients in care
  - Ongoing stigma (especially against people who inject drugs) and lack of care in Corrections
  - High price of HCV regimens

1. https://www.ncbi.nlm.nih.gov/books/NBK368067/

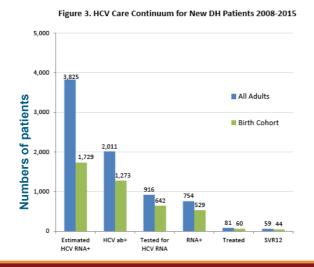
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## Fewer than 5% of Patients with HCV Infection Were Treated at Denver Health



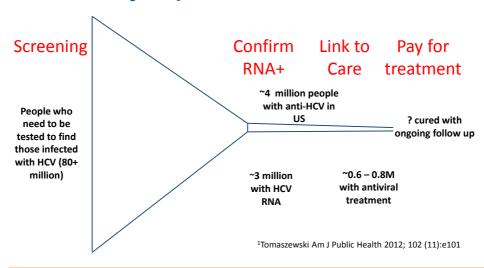
Retrospective review of HCV care at Kaiser Permanente Colorado and Denver Health found that fewer than 5% of the estimated population with HCV infection who were newly diagnosed from 2008 through 2014 were treated. Indicates lack of necessary testing and linkage to care.

Rowan SE, Durfee J, Tabano DC, et al. The association between HCV and comorbid conditions in 2 large patient cohorts. CROI, February 13-16, 2017, Seattle. #528

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## Many Gaps in HCV Care Cascade



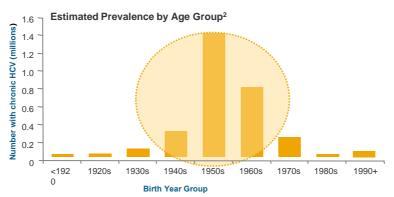
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# 75% of People with Hepatitis C in the U.S. are Baby Boomers

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## Baby Boomers (Born in 1945–1965) Account for 76.5% of HCV in the U.S.



An estimated 35% of undiagnosed baby boomers with HCV currently have advanced fibrosis (F3-F4; bridging fibrosis to cirrhosis)<sup>3</sup>

 Centers for Disease Control and Prevention. MMWR. 2012;61:1-32; Adapted from Pyenson B, et al. Consequences of Hepatitis C Virus (HCV): Costs of a baby boomer Epidemic of Liver Disease. New York, NY: Milliman, Inc; May 18, 2009. http://www.milliman.com/expertise/healthcare/publications/rr/consequences-hepatitis-c-virus-RR05-15

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#### Who Should Be Tested for HCV?

#### **CDC Recommendations**

- Everyone born from 1945 through 1965 (one-time)
- Persons who ever injected illegal drugs
- Persons who received clotting factor concentrates produced before 1987
- Chronic (long-term) hemodialysis
- Persons with persistently abnormal ALT levels.
- Recipients of transfusions or organ transplants prior to 1992
- Persons with recognized occupational exposures
- · Children born to HCV-positive women
- HIV positive persons
- \*Only pertains to persons with normal liver enzymes; if elevated liver enzymes need HBV and HCV testing

#### **USPSTF Grade B Recs\***

- Everyone born from 1945 through 1965 (onetime)
- · Past or present injection drug use
- Sex with an IDU; other high-risk sex
- Blood transfusion prior to 1992
- Persons with hemophilia
- · Long-term hemodialysis
- Born to an HCV-infected mother
- Incarceration
- Intranasal drug use
- · Receiving an unregulated tattoo
- · Occupational percutaneous exposure
- Surgery before implementation of universal precautions

Smith at al. Ann Intern Med 2012; 157:817-822. Moyer et al. Ann Intern Med epub 25 June 2013

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## Beth Israel Deaconess Baby Boomer HCV Testing Program

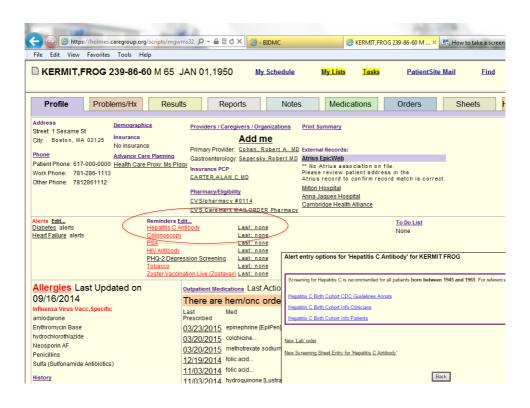
#### **Assembled a Core Team**

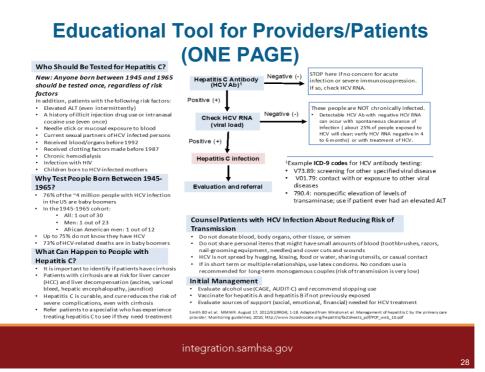
 Primary Care, Infectious Disease, Hepatology, Information Systems (EHR), and Laboratory Medicine

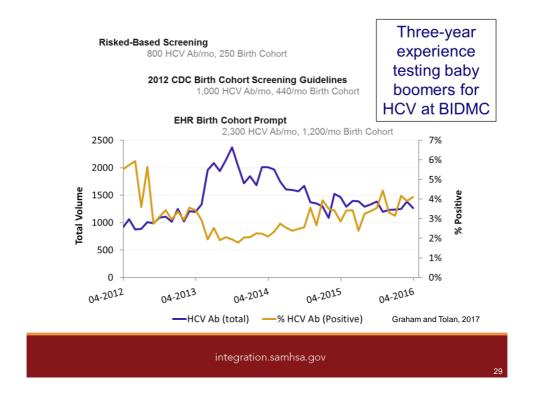
#### **Collaboration with Laboratory Medicine**

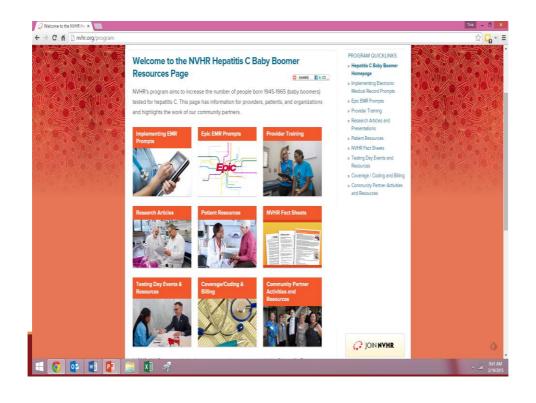
- Expand capacity for increased volume: HCV Ab and RNA viral load testing
- 2. Provided a database report of all positive HCV Ab tests for Nurse Educator
- 3. Subsequently added report comment indicating "Recommended follow-up for positive HCV Ab results is viral load testing"

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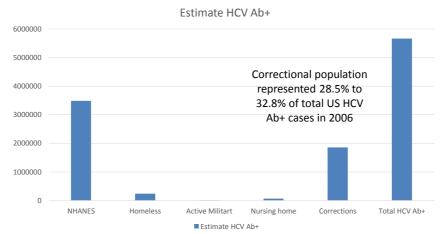
## **Populations Still Being Left Behind**

- People born outside the 1945-1965 birth cohort (25%)
- · People outside health care system
- Incarcerated
- People who inject drugs (PWID)
- Indian Health Services (IHS) covered patients

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## We need to test people where they are, such as prisons



Varan, Public Health Rep 2014; 129:187

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## **Treating HCV in PWID**

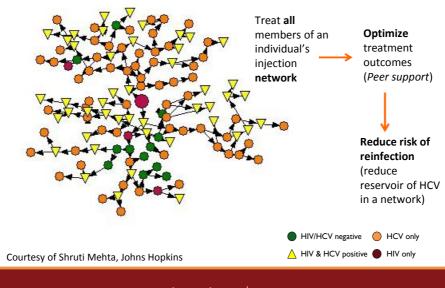
- We have to treat PWID for their own health and to reduce HCV transmission
- People will get re-infected
  - If nobody gets re-infected, we have not been treating the right patients to reduce transmission
- Treating small numbers of patients increases the risk of reinfection
  - · Reinfection will increase before it decreases

Negro, CROI 2016.

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## **'Bring Your Friends' Approach May Optimize Treatment and Prevention Outcomes**



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#### **HCV Treatment**

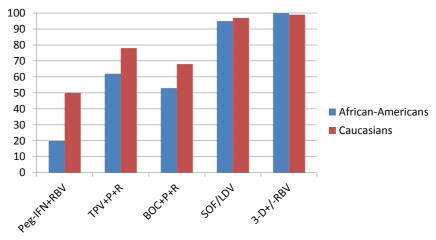
- Seven FDA-approved regimens for genotype 1
  - Three regimens can be used for genotypes 2 and 3
  - A few subgroups require ribavirin (anemia)
- Selection often guided by insurance restrictions
- · Most patients receive 12 weeks
- Most receive 1 -3 pills once a day
- All patient groups have a >90% SVR (virological cure) rate, including previously difficult-to-cure
  - · HIV, post-liver transplant, liver failure, dialysis

www.hcvguidelines.org

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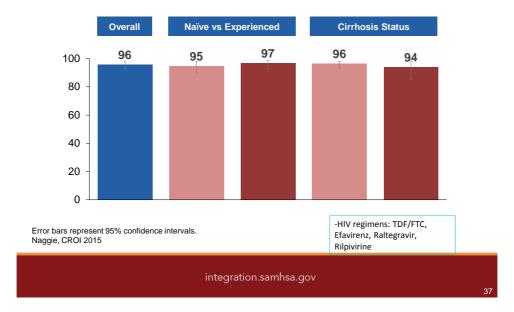
### African American Patients Have Similar Cure Rates as Caucasians with All-Oral Treatment



Graham, JAMA 2015

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## Results: SVR12 by Prior Treatment Experience and Cirrhosis Status HIV-HCV (ION-4)



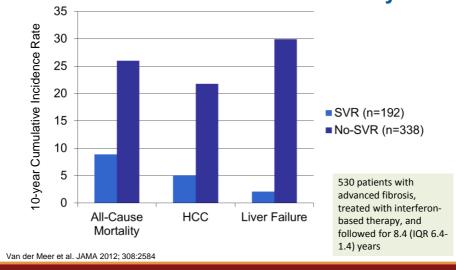
## Drug-Drug Interactions with HIV and HCV Meds (Examples)

	Grazoprevir/Elbasvir	Ledipasvir	Velpatasvir	Paritapreivr/r/Ombitasvir + Dasabuvir
Ritonavir-boosted atazanavir	GZR 个, EBR 个, ATV 个	LDV 个; ATV 个 (avoid TDF)	VEL 个; ATV 个 (avoid TDF)	PTV 个; AVT 个
Ritonavir- boosted darunavir	$GZR \uparrow$ , $EBR \uparrow$ , $DRV \leftrightarrow$	LDV $\uparrow$ ; DRV $\leftrightarrow$ (avoid TDF)	$\begin{array}{c} \text{VEL} \longleftrightarrow \text{; DRV} \longleftrightarrow \text{(avoid} \\ \text{TDF)} \end{array}$	PTV ↑/↓; DRV ↓
Cobicistat-boosted elvitegravir	No data	LDV 个; Cobicistat 个 (avoid TDF)	VEL 个; Cobicistat 个 (avoid TDF)	No data
Efavirenz	$GZR \downarrow$ , $EBR \downarrow$ , $EFV \downarrow$	LDV $\downarrow$ ; EFV $\downarrow$ (and TDF $\uparrow$ )	VEL ↓; EFV ↓	No PK data (stopped due to toxicity)
Rilpivirine	$GZR \leftrightarrow$ , $EBR \leftrightarrow$ , $RPV \leftrightarrow$	$LDV \leftrightarrow$ ; $RIL \leftrightarrow$	$VEL \leftrightarrow ;RIL \leftrightarrow$	PTV 个; RIL 个 (prolonged QTc)
Raltegravir	$GZR \longleftrightarrow$ , $EBR \longleftrightarrow$ , $RAL \uparrow$	$LDV \leftrightarrow ; RAL \leftrightarrow$	$VEL \longleftrightarrow ; RAL \longleftrightarrow$	PrOD ↔; RAL ↑
Dolutegravir	$GZR \leftrightarrow$ , $EBR \leftrightarrow$ , $DTG \uparrow$	$LDV \leftrightarrow$ ; $DTG \leftrightarrow$	$VEL \;{\longleftrightarrow} ; \; DTG \;{\longleftrightarrow} \;$	PTV ↓; DTG ↑
Tenofovir disoproxil fumarate	$GZR \leftrightarrow$ , $EBR \leftrightarrow$ , $TFV \uparrow$	LDV ↔; TFV ↑	VEL ↔; TFV ↑	$PrOD \leftrightarrow ; TFV \leftrightarrow$
Tenofovir alafenamide	No data	LDV ↔; TVF ↑	VEL ↔; TFV ↑	No data

Kiser JJ, www.HCVguidelines.org

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## **SVR (Cure) Associated with Decreased All-Cause Mortality**



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## FibroScan - Transient Elastography Liver biopsies are rarely performed

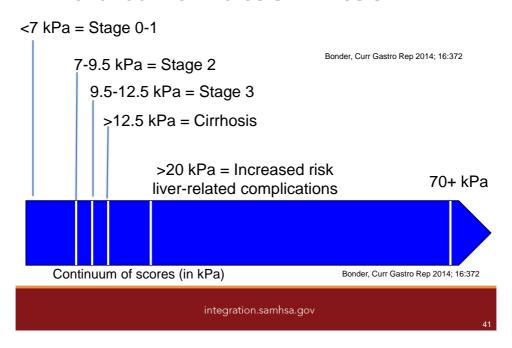
- Ultrasound determines velocity of shear wave in m/s, which is proportional to liver stiffness in kilopascal (kPa)
- Entire process requires 15 to 20 minutes, provides immediate results
- Falsely elevated results:
  - High ALT (>100)
  - Eating within 2 hours

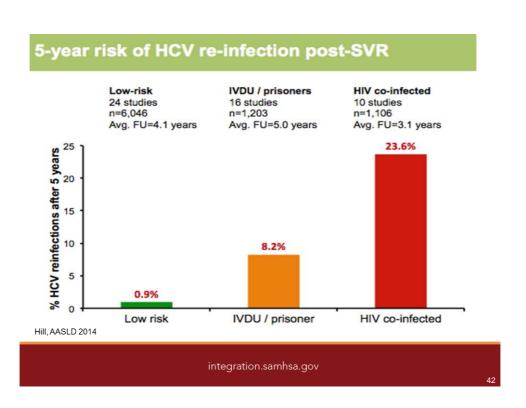
Bonder, Curr Gastro Rep 2014; 16:372



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#### Continuum of Fibrosis/Cirrhosis in HCV





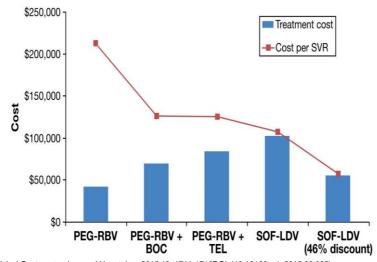


## **Current Negative Environment Created By High Price of HCV Drugs**

- Confusion and doubt among HCV treaters
- Fear from PCPs about testing and treatment
- · Fear/outrage among payers (public and private)
- Hesitation in DPH/public outreach programs
  - Difficulty establishing broad baby boomer testing programs
- Declarations by prisons, states' Medicaid that HCV treatment is not of value
- Rationing of treatment, i.e. F3-F4; substance use
  - Justification for overt discriminatory practices like mandating clean urine samples
- No discussion of cure-as-prevention
- Loss of vision about transformative, curative developments
- Confirmation by patients that they are not "worth" treatment

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## Price per SVR has Decreased in the U.S.



Clinical Gastroenterology and Hepatology 2015 13, 1711-1713DOI: (10.1016/j.cgh.2015.06.005)

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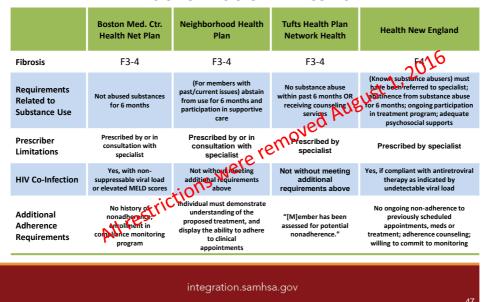
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### **Limitations on Access to HCV Treatments**

- · Limits Based on Stage of Fibrosis
- Restrictions Based on Substance Use
- Prescriber Limitations
- Other restrictions
  - HIV Co-Infection limitations
  - "Once per lifetime" limitations
  - Genotype limitations
  - Previous history of treatment adherence requirements
  - Specialty pharmacy restrictions
  - · Exclusivity agreements with insurers

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## MassHealth MCOs Sovaldi Prior Authorization Criteria





- The people most affected by viral hepatitis can be hard to reach.
- People with the most serious need for health care, including people with behavioral health problems, need more support services.

The Department of Health and Human Services should work with states to build a comprehensive system of care and support for special populations with hepatitis B and C on the scale of the Ryan White system.

BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE

The National Academies of SCIENCES · ENGINEERING · MEDICINE

The National
Academies of
Sciences
recognizes the
important of
support services
for the success
of a US viral
hepatitis
elimination
strategy

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#### **Conclusions**

- Hepatitis C can be eliminated in the U.S.
- · Requires increasing education, screening, diagnosis, linking patients to care,
- · Increasing resources targeted to prevention, access to antiviral treatment, and follow up
- All steps in the HCV care continuum may be improved with patient support
- · Advocacy for increased resources for this curable disease will be important

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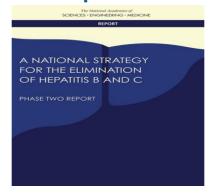
## **Q&A** and Group Discussion





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## Resource: A National Strategy for the Elimination of Hepatitis B and C



Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2017. A national strategy for the elimination of hepatitis B and C. Washington, DC: The National Academies Press.

http://www.nationalacademies.org/hmd/reports/2017/nationalstrategy-for-the-elimination-of-hepatitis-b-and-c.aspx

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## MAI-COC Community of Practice Session #3: Sharing Integration Innovations

Thursday, April 27 3:00 - 4:30 PM ET

https://attendee.gotowebinar.com/register/586558045438 0571138

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